



Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Required Report - public distribution

Date: 1/4/2002

GAIN Report #EC2001

Ecuador

Food and Agricultural Import Regulations and Standards

Country Report

2002

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Report Highlights:

Ecuador maintains reasonable import regulations and standards for both food and agricultural imports, mostly based on international standards. Although inefficiency of certain government institutions continues to create problems, several changes have been put in place dealing specially with the registration of processed food products.

Includes PSD changes: No
Includes Trade Matrix: No
Annual Report
Lima [PE1], EC

FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS (FAIRS)

"This report was prepared by the Office of Agricultural Affairs of the USDA/ Foreign Agricultural Service in Quito, Ecuador for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign costumers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY."

TABLE OF CONTENTS

SECTION I. FOOD LAWS

Official Register	4
Ministry of Agriculture and Livestock (MAG)	4
Agricultural Development Law	4
Plant Health Law	4
Animal Health Law	5
Law of Seeds	5
Law for the Formulation, Manufacture, Import, Trade and Use of Pesticides and Similar Products of Agricultural Use	5
Dependencies of the Ministry of Agriculture and Livestock	5
Ecuadorian Animal and Plant Health Service (SESA)	5
Domestic and International Trade Directorate	6
Agricultural and Livestock National Directorate	6
Ministry of Public Health	6
Health Code	6
Sanitary Permit Regulation	6
Food Regulation	6
Organic Law of Consumer Defense	6
<i>Other Institutions Related to Foreign Trade</i>	7
Ministry of Foreign Trade, Industrialization and Fishing (MICIP)	7
Law of Foreign Trade	7
Ecuadorian Normalization Institute (INEN)	7
Ministry of Foreign Affairs	8
Ecuadorian Customs Corporation (CAE)	8

SECTION II. LABELING REQUIREMENTS	8
a. General Requirements	8
b. Requirements Specific to Nutritional Labeling	10
Exceptions and Special Dispositions regarding Obligatory Nutritional Labeling	10

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS	11
---	----

SECTION IV. FOOD ADDITIVE REGULATIONS	11
---------------------------------------	----

SECTION V. PESTICIDE AND OTHER CONTAMINANTS	12
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SECTION VI. OTHER REGULATIONS AND STANDARDS	12
a. Sanitary Permit (For processed food products and additives)	12
b. Phytosanitary and health permits (For agricultural and animal products)	14
Phytosanitary or Health certificates of Import	14
Other Requirements	15
c. Register of Agricultural and Livestock Inputs	15

Control of products at retail- wholesale distribution levels	15
SECTION VII. OTHER SPECIFIC STANDARDS	16
a. Wine, Beer and Other Alcoholic Beverages	16
b. Product Samples and Mail Order Shipments	16
SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS	17
a. Trademarks	17
b. Brand names	18
SECTION IX. IMPORT PROCEDURES	18
Agricultural and Livestock Products Import	19
APENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS	20
APENDIX II. OTHER IMPORT SPECIALIST CONTACTS	23

SECTION I. FOOD LAWS

Ecuador's Foreign Trade Law prohibits any economic, administrative or technical practice aimed at putting limits or discouraging foreign and internal trade, free competition and local production of goods and services. Also, the referred law allows the application of corrective measures in all cases included in the World Trade Organization normative.

Nonetheless, Ecuador maintains barriers interfering with imports. Although imports in Ecuador are not subject to excessive tariffs, and other technical restrictions are supposed to be established with the only purpose of protecting human, animal and plant health; problems rise because of the inefficiency of certain government institutions and other organizations. Administrative procedures take too much time, and new requirements as well as documents are requested every time.

Official Register

Every law issued by the National Congress and approved by the President; decrees, agreements or resolutions approved by the National Congress; other regulations issued by agencies and institutions of the legislative, executive or judicial power and the Electoral Supreme Court; and, decisions made by the Constitutional Room of the Supreme Court come into legal effect on the day after their publication in the "Official Register", unless a specific date had been established for this purpose.

The "Official Register" is the official legal publication of Ecuador. It was established in the First Constitution of 1830 with the name of "Official Diary" and its purpose is to inform all the population about any law, decree, agreement or other disposition that affect them. Currently, it is mainly sold in Quito, and its cost is US\$0.20.

Ministry of Agriculture and Livestock (MAG)

The Ministry of Agriculture and Livestock is charged with promoting harmonic and sustained development of the agricultural and livestock sectors of Ecuador, through orientation, direction and evaluation of agricultural ~~and livestock~~ activities. The laws by which this agency is ruled are mainly the following:

Agricultural Development Law

This law was published in the Official Register #55 on April 30th, 1997 and guarantees free import and trade of inputs, ~~improved seeds~~, improved plants and animals, machineries, equipment and technology, except for those which have been qualified by the country of origin as inconvenient or noxious for the ecological or environmental preservation.

Plant Health Law

This law, published in the Official Register # 475 on January 18th, 1974, is aimed at preventing and controlling plagues, illnesses and pests that may affect the agricultural crops. This norm establishes regulations, conditions and prohibitions for imports and exports of plant products.

Animal Health Law

The Law of Animal Health, published on the Official Register # 409 on March 31st, 1981, has the objective of preventing, controlling and eradicating illnesses in the national livestock. This Law points out that the Ministry of Public Health, along with the Ministry of Agriculture and Livestock, must control the quality of animal origin products destined for human consumption. Also, these two institutions must prohibit trade or retire from the market those products harmful to human health. The law also states the obligation of obtaining previous authorization and a certificate from the Ministry of Agriculture and Livestock for importing and exporting cattle and other animal origin products and sub-products.

Law of Seeds

This law is related to all requirements for importation and exportation of seeds. It also mentions the obligation of importers and exporters to register as such in the Ministry of Agriculture and Livestock. Furthermore, this law **regulates commercialization of seeds and seeds products.**

Law for the Formulation, Manufacture, Import, Trade and Use of Pesticides and Similar Products of Agricultural Use

This law establishes the obligation of every person or company importing, manufacturing or distributing pesticides and similar products for agricultural use, to register at the MAG for such purposes. It also rules transportation, storage, labeling and advertisement of these products. The law determines tolerance residue levels for pesticides.

Institutions and Dependencies of the Ministry of Agriculture and Livestock (MAG)

Ecuadorian Animal and Plant Health Service (SESA)

SESA's basic purpose is to ensure health of agricultural crops, animal population, and plant breeding and livestock genetics, impeding the entry to the country of exotic pests, and the increment and the dissemination of those already existing.

Among its duties, it must demand the fulfillment of legal norms and international and sub regional techniques that regulate import, manufacture, formulation, distribution, trade and use of pesticides, veterinarian products and agricultural products.

This agency is in charge of the issuance of the Phytosanitary permit or health permit, depending on the case, for imported products and sub products of plant or animal origin, and animals and **plant breeding material**

Domestic and International Trade Directorate

This directorate is responsible for analyzing and suggesting changes to the legislation when it limits free trade of agricultural products. It also suggests changes to laws and rules concerning trade and financing of agricultural commercial activities.

Agricultural and Livestock National Directorate

Main responsibilities of this agency are:

- a. Establish requirements for manufacture, formulation, import and trade of fertilizers, **animal feed** and seeds.
- b. Quality control of fertilizers, **animal feed**, seeds and vegetal obtainment internally traded.

Ministry of Public Health

The Ministry of Public Health, through the National Control and Surveillance System, and its dependencies, regulates the entry and consumption of processed food products, beverages, additives and pesticides.

The Health Code

The health code establishes the obligation of obtaining the Sanitary Register (sanitary permit) prior to import, trade, production, storage or transportation of processed food, additives, and pesticides for domestic, agricultural or industrial use. According to this law, the Ministry of Public Health (MSP) and its agencies are responsible for all processed foods and additive inspection.

Sanitary Permit Regulation

This document contains all necessary conditions, requirements and procedures for issuance, suspension or cancellation of the Sanitary Permit.

Food Regulation

These rules describe all requirements that food products need to fulfill in order to be offered to consumers, as well as the manufacture, container, packaging and labeling requirements needed to be fulfilled. Moreover, the food regulation governs the activities of transportation, distribution and trade concerning food products.

Organic Law of Consumer Defense

This law's objective is to guarantee consumer's right to obtain quality, regularity and fair prices in goods and services offered to them in the market. The dispositions of this law are applicable to all persons and companies from the private or public sectors producing, importing, exporting or distributing goods and services.

This law establishes the obligations and responsibilities that all suppliers have towards consumers, among these, the obligation of providing clear, complete and enough information about their products. It also determines the minimum information in a product's label, including price in local currency and indications about the content and weight of the product, expressed in Standard International Units of Measurement. It states that potentially dangerous products for health or physical integrity, must show all necessary indications or warnings.

OTHER INSTITUTIONS RELATED TO FOREIGN TRADE

Ministry of Foreign Trade, Industrialization and Fishing (MICIP)

The Ministry of Foreign Trade, Industrialization and Fishing is the government agency responsible for planning, directing, controlling and executing policies for foreign trade, industrialization, fishing, small industry, medium industry, little businesses and ships. Its mission is to improve business in Ecuador, facilitating domestic and international **competitiveness** of the productive sectors.

Law of Foreign Trade

This law rules activities carried out by the MICIP, it was published in the Official Register #82 on June 9th of 1997. The law prohibits any practice or administrative disposition that limits free competition or obstructs development of domestic and international trade and production. Nevertheless, the law allows corrective actions to be applied in cases contemplated under the regulations of the World Trade Organization (WTO). In spite of that, the inefficiency of certain public agencies and other institutions block an adequate development of import activities. Examples of this could be the National Health and Tropical Medicine Institute "Leopoldo Izquieta Pérez", co-responsible for the issuance of the sanitary permit and the Ecuadorian Customs Corporation (CAE), which administrates customs services.

Ecuadorian Normalization Institute (INEN)

INEN is an agency of the **Ministry of Foreign Trade, Industrialization and Fishing (MICIP)** and is responsible for:

- Prepare Ecuadorian technical standards defining characteristics of raw materials, intermediate products and finished products traded in Ecuador. Also, INEN must formulate the methods for

assay, inspection, analysis, measurement, classification and denomination of such materials or products.

- Administrate the **Quality Certification System**.
- Implementing the Standard International Units of **Measurement (SI)**.
- Inspecting the fulfillment of requirements set in the Ecuadorian Technical Standards NTE for imported and local products.

Ministry of Foreign Affairs

The Ministry of Foreign Affairs collaborates with the President of the Republic and coordinates with MICIP and MAG in the formulation of international policies, direction of international affairs and celebration of agreements and other international conventions. It is responsible for supporting commercial negotiations and offering assistance in the solution of controversies.

Ecuadorian Customs Corporation (CAE)

Customs services are administrated by the Ecuadorian Customs Corporation (CAE). This agency is responsible for the surveillance and control of the entrance or departure of persons, commodities, and means of transportation through the borders and ports of Ecuador, and the assessment and collection of import duties and taxes. All activities carried out by the CAE are governed by the Organic Law of Customs and its respective Regulation.

SECTION II. LABELING REQUIREMENTS

a. General Requirements

The Health Code, the Sanitary Permit & Food Control Regulation, and the Technical Standard NTE INEN 1334-1, provide labeling requirements for processed food products.

Containers must have a visible printed or tagged label with the following minimum information in Spanish:

a) Name of the Product: Must be specific and indicate the product's real nature.

b) Brand Name

d) List of Ingredients: **All ingredients must be listed by their common name in descending order of predominance** by weight.

e) Net content and drained mass (net weight of product): Has to be declared in **Metric System (SI) as follows:**

- Powdered, dry or solid food products shall display net weight.

- Liquid food products shall display net volume.
- Semi- solid or semi-liquid food products can display either weight or net volume.

f) Identity of manufacturer, packager or importer: In the case of imported products, the name and address of the importer, distributor and/or legal representative must appear too.

g) City or Country of origin: In order to identify the country of origin, one of the following statements should be used: "Fabricado en USA", "Producto de los Estados Unidos..." o "Industria Estadounidense".

h) Lot Identification

i) Date and Storage instructions:

- It is necessary to declare shelf- life date and/or expiration date.
- Expiration date must show day/month for products with shelf- life of 3 months or less; and month/year for products with shelf- life of more than 3 months. The expiration date must to be accompanied by one of the following expressions: "Consumir preferentemente antes de...", "Vence en...", "Consumase antes de...", "Fecha de expiracion...", "Expira en...".
- It is not mandatory to show expiration date in labels of wine, liquor wine, aromatized wine, fruit wine & fruit sparkling wine, and alcoholic beverages containing 10 percent or more alcohol per volume.
- Also, the label must present any other specific storage requirement necessary to keep the product safe.

j) Instructions for Use

When a food product needs refrigeration or freezing during its storage it is mandatory for the label to show the legend "Mantengase en refrigeración" or " Mantengase en congelación" indicating, whenever possible, the temperature at which it has to be stored. When a food product requires special conditions of storage and transportation, these must be clearly indicated in the label or external package.

k) Sanitary Registration Number

l) Price (P.V.P)

m) Others

In addition to the requirements listed above, Ecuadorian labeling standards also acknowledge the following guidelines:

- **Labels containing words, pictures or other graphic representations presenting the product as of medicinal, therapeutical, preventive, curative, nutritional, or especial faculties, and which may misrepresent the real nature, origin, composition or quality of the product are not allowed.**

- When a product is very small size or if because of its nature, it is not possible to show all the information required in a food label, this information must be presented in a package that contains several unities of the product.
- Imported products may have labels in foreign language with the respective translation in Spanish, in the same form and characters, and containing all previously listed requirements. The foreign label must be applied prior to export, because the product has to enter the country in its final presentation.
- The Solid Waste Management regulation determines that every product's label must promote **recycling**, recuperation or re-use of the package or container.
- Ecuadorian standards do not differ significantly from those established by the United States; they are based on the Codex Alimentarius and FDA (Food and Drug Administration) stipulations.

b. Requirements Specific to Nutritional Labeling

The technical standard NTE INEN 1334-2 refers to minimum requirements needed to be met for nutritional labeling of every processed food product, offered as such for sale. This standard gathers the declaration of nutrients and explains that the complementary nutritional information is optional.

The bases of this standard are the Codex Alimentarius and the FDA guidelines, for which, U.S. standards are acceptable. Recommended Daily Intake (RDIs) is based on the Recommended Daily Intake of nutrients of the **FAO**/ IHO.

Exceptions and Special Dispositions regarding Obligatory Nutritional Labeling

Foods Containing Insignificant Quantities of Nutrients

An insignificant quantity is defined as that which allows the declaration of "Zero", except for total carbohydrates values, dietetic fiber and protein, for which an insignificant quantity is less than one gram. Products that complying with this exception includes: grain coffee, tea leaves, soluble tea and unsweetened coffee, dehydrated vegetables for seasoning, extracts of flavors and colorings for food.

Baby Food

There are specific labeling requirements and technical standards for baby formulas.

Dietetic Supplements

This exception does not apply for dietetic supplements in the form of conventional foods, such as breakfast cereals. These products are subject to all requirements specified in NTE INEN 1334-2

Packed Food

These products are exempt only if they are shipped in bulk and are not for direct sale to the consumer, but are imported for use in processing industries. Example: Bulk-packed sweet corn to be re-packed in a vegetable mix

Fresh Food Products

Fresh Food (fresh fruits and vegetables) and Seafood (fresh fish and seafood).

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

The food regulation establishes that food containers must meet the following conditions:

- It should have adequate shape, capacity and closing **seal** for the contained food product.
- The container should be made of materials in relation with the physical-chemical nature of its content.
- Containers must guarantee the protection, conservation and identification of the product during its shelf- life.

The materials used in the containers and packages for a processed food product must meet the conditions established in specific **Ecuadorian Technical Standards (NTE) for a product or group of products**. Moreover, the Solid Waste Management regulation asserts that all packages and containers must be made of materials that allow their after-use **recycling**, recuperation or re-use.

SECTION IV. FOOD ADDITIVE REGULATIONS

Standards and regulations for food additives are those contained in the Health Code, the Food Regulation and the technical standard NTE INEN 2074-96. The Food Regulation establishes that food additives are allowed for importation and in-country sale when:

- They are innocuous for human health; and,
- They have obtained the Sanitary Permit.

The technical standard NTE INEN 2074:96 is based in the Codex Alimentarius and the Regulation Code of the Food Drug Administration (FDA). It establishes a positive additive list, specific regulations about tolerance levels, and a list of prohibited substances for human consumption. This positive list will be periodically checked and/or modified according to new scientific, technological and toxicological studies.

The NTE INEN 2074-96 standard, as well as other technical norms, are available for public sale. U.S.

exporters can obtain a copy sending a request to the Ecuadorian Institute of Normalization (INEN). However, these norms are written in Spanish and there are no English copies available.

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

The Law of Formulation, Manufacture, Import, Trade and Use of Pesticides and Similar products was established to guarantee integrity of pesticides, their quality and chemical composition to be declared by the manufacturers, importers and distributors. The Ministry of Agriculture, through the Administrative Unit of Plant Health, is the agency in charge of the application of this law.

Ecuador has not set its own maximum tolerance levels. In fact, it applies Codex maximum residue limits. Other maximum levels established by international institutions widely recognized are also acceptable, such as those from the Environmental Protection Agency (EPA).

The Ministry of Agriculture and Livestock (MAG) will temporarily retain agricultural products suspected of being contaminated with pesticides or similar products. If analysis carried out by MAG proves this to be the case, the Ministry will order their destruction and no indemnification will be granted.

SECTION VI. OTHER REGULATIONS AND STANDARDS

a. Sanitary Permit (For processed food products and additives)

In order to protect consumers' health, the actual Health Code establishes that all national or foreign processed food products and additives must obtain a Sanitary Permit prior to their importation and sale in Ecuador. The sanitary permit issuance process has been re-designed, and new laws have been written on this matter. The recently released Sanitary Permit Application Rules give the following guidance:

- The sanitary permit can either be requested by the manufacturer or its legal representative, and in both cases, the permit will be issued to the name of the manufacturer unless it legally pronounces on the contrary.
- The sanitary permit will be valid for ten (10) years.
- The sanitary permit for imported products will be granted by homologation after 30 calendar days of having delivered an application accompanied by all necessary documents at any office of the National Hygiene Institute "Izquierda Perez" (NHI). Observations will be directed to the applicant five (5) days after the NHI received the application.
- Currently, the applicant must submit the following documents:
 1. Request form (obtained at the NHI) including the following information:

- 1.1. Complete product name, including brand-name
- 1.2. Name, complete address and telephone number of the manufacturer
- 1.3. Name and address (in full) of the applicant
- 1.4. Product Description:
 - 1.4.1 Ingredients list (qualy-quantitative formula, in percentages) used in the product (including additives), declared by the manufacturer in descending order.
 - 1.4.2 Elaboration date
 - 1.4.3 Expiration date or maximum consumption time
 - 1.4.4 Packaging Information: must declare type of container, and content expressed in units of the International Measurements System (SI).
 - 1.4.5 Conservation conditions
- 1.5 Applicant's signature accompanied by the signature of the product's technical representative in Ecuador (a food pharmaceutic chemist or food engineer registered at the Ministry of Health)
2. The applicant must include a copy of his/her identification document (in the case of persons), or an existence certificate accompanied by the legal representative appointment (in the case of a company).
3. Free Sale Certificate issued by a competent health authority in the exporting country stating that the product is authorized for free sale and consumption in that country.
4. Product analysis certificate issued by its manufacturer or the competent health authority in the country of origin. A certificate of quality would be ideal.
5. A legalized statement signed by the manufacturer regarding the following:
 - 5.1 The representation of the product in Ecuador
 - 5.2 Ownership of the sanitary permit.
6. Product's label or tag draft (original and copy).
7. Invoice for payment of registration fees
8. Every official certificate issued abroad must be legalized by the Consul of Ecuador in the exporting country or the Ministry of Foreign Affairs (once in Ecuador).

Notes:

1. All documents and certificates written in languages other than Spanish must be translated and notarized.
2. It is recommended by the National Board of Health Control for imported products sanitary permit applications to be filed at the (NHI) in Quito rather than in Guayaquil.

A new Sanitary Permit will be necessary in the following events:

- If there is a change in the composition.
- The product needs a different conservation process.
- There is a substantial modification of the following additives: colorings, flavorings, sweeteners, conservation agents, nutritional additives.
- Changes in the nature of the container
- Change of manufacturer.

b. Phytosanitary Permit and Health Permit (For Agricultural and Animal Products)

Current laws obligate importers of **plant breeding material**, products and sub-products of plant and animal origin to obtain a Phytosanitary Permit and Health Permit (depending on the case), prior to importing. Consequently, it is necessary to file the following documentation at the **Under-secretariat for Policy, Commerce and Investment of** MAG in Quito:

- **The Unique Import Document** (DUI) (See Section IX. Import Procedures)
- Note of Requisition (original and three copies).
- Pro-forma Invoice (original and three copies)
- "Previous Import Authorization" form (original and three copies), correctly filled by the interested part. It is available in any bank of the country.
- For importation of animals and other products of animal origin, the importer must include a payment receipt of the import fee at the National Development Bank (BNF).
- An individual or collective PEDIGREE certificate must be included for importation of pets and breed animals. The Pedigree Certificate will be analyzed and checked by the **Agricultural and Livestock National Directorate** in Quito and the **Undersecretary of the Coastal Region** in Guayaquil, depending on the case.

The **Ecuadorian Animal and Plant Health Service** (SESA) will check the documentation and will issue the phytosanitary or health permit, depending on the product. If the documents were not correct, SESA will return the application to the Under Secretary of Policy and Investment indicating that such import is not authorized.

In the phytosanitary and health permits, SESA will indicate the treatment and conditions to be met by the product in order to enter the country, depending on preestablished phytosanitary and health norms.

Phytosanitary or Health Certificates for Import

Every imported agricultural or livestock product must be accompanied by a phytosanitary or health certificate, issued in the country of origin by the competent authority.

Other Requirements

The phytosanitary certificate is issued by SESA. However, there are other requirements to be fulfilled for importation of plant products and plant material:

- a) The product must be free of soil and products in animal or vegetal decomposition.
- b) Use of poor quality, re-used, infected or infested package material is not allowed.
- c) The **plant breeding** material must come from a country or area known to be free of pathogens exotic to Ecuador.
- d) Given the case, SESA shall request the product to be accompanied by a Fumigation Certificate or Quarantine Treatment, signed by the competent authority of the country of origin.

In the case of animal imports, the following requirements must be met:

- a) Animals must come from zones in which no infect-contagious illnesses affecting the specie were detected, during a specific period previous to the shipment established for each illness.
- b) Animals must have been opportunely immunized with all the vaccines required by Ecuador through SESA authorities.
- c) Results of laboratory tests and exams carried out to investigate the presence of infect-contagious illnesses should be negative, and;
- d) Animals should have received treatment against ecto parasites and endo parasites, and they should be in good physical conditions without clinic symptoms of infect-contagious illnesses.

c. Register of **Agricultural and Livestock Inputs**

Every person or company interested in importing and/or producing **agricultural and livestock inputs** (seeds, plants and plant breeding material, **improved** animals, semen, fertile eggs and embryos) must register themselves in the SESA or in the **Agricultural and Livestock National Directorate** at MAG. The validity of the registration is indefinite, but it can be canceled because of non compliance with the dispositions stated in the Law of Seeds and in its respective regulation.

Control of products at retail/wholesale distribution levels

The Ministry of Health has the obligation of controlling processed food products and additives used in the food industry at the places of sale. If a product does not meet the minimum quality standards, or does not have a Sanitary Permit, it could be immediately confiscated or/and destroyed.

The Ministry of Public Health in coordination with the Ministry of Agriculture, will control the products of animal origin destined to human consumption and will prohibit or retire from trade those resulting harmful to human health.

The Ministry of Agriculture and Livestock, through employees of the Plant Health Directorate or other designed persons may inspect commercial or industrial facilities storing and selling seeds to verify the health

status of the **plant breeding material**. If plant pests or outbreak infectious disease are in place, the staff can declare "Observation Zone" or "Quarantine" depending on the seriousness of the case, and if it is necessary they can order the incineration of the infected or infested material.

SECTION VII. OTHER SPECIFIC STANDARDS

a. Wine, Beer and Other Alcoholic Beverages

Imports of alcoholic products, including beers, will be carried out exclusively from the country of origin and by the legally authorized representatives, previous to the obtainment of the correspondent Sanitary Register. Imports of these products must meet the regulations PyM 1992-20, PyM 1992-17, PyM 1992- 21 from INEN regarding allowed containers. Alcoholic products and beer must necessarily show the following information on their frontal label:

"Importado por (Name of the representative or agent)", alcohol grade and the capacity of the bottle in cubic centimeters.

Also the following health advisory has to be included:

"Advertencia: El consumo excesivo de alcohol causa graves daños en su salud y perjudica a su familia. Ministerio de Salud Pública", that must be written in the principal or secondary label, meeting disposition 1828 of the Decree dated June 10th, 1994.

Alcoholic products and imported beers sold in the national market without complying with these requirements, will be considered as smuggled into the country.

b. Products Samples and Mail Order Shipments:

Samples Import and Export regulations establish that these are exempt from the payment of **import duties**, Value- Added Tax (IVA) and Special Consumption Tax (ICE), when the CIF value does not exceed from US\$ 500 or its equivalent in other currencies. Merchandise exceeding this value will pay (for the excess) the tariff established for imports.

Samples without commercial value must meet the following requirements in order to obtain this exemption:

- a) The sender shall be the producer of the merchandise, its representative or the authorized exporter;
- b) The **addressee** shall be a company or an importer habitually dedicated to this commercial activity.
- c) The documentation (commercial invoices, transportation invoices or others concerning the shipment), shall contain annotations demonstrating the products are certainly samples without commercial value; and,
- d) Samples must show legends, signs or impressions identifying themselves as samples without commercial value and forbidding sale. In case of doubt, the Customs Administration may mark the samples with perforations, seals and others in order to impede their sale.

Correspondence and little packages are also exempt of taxes, according to the Regulation at which Mail or Courier and International Postal Traffic Agencies are subject. Other types of packages and international postal **cargo** that departing or entering the country, with or without commercial purposes and made by any type of mail agency, are subject to the payment of the corresponding taxes, in relation to the CIF value.

In the same way, little packages, packages and postal **cargo** and samples without commercial value, exempt or not of taxes, whose CIF values do not exceed \$160 will be dispatched by **customs** through a simplified declaration.

Imports or exports by mail of products such as: narcotics, explosives, tobaccos, liquors, inflammable products and other dangerous or contaminant substances are forbidden.

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

The Law of Intellectual Property, published in the Official Register on May 19th of 1998, regulates and guarantees the intellectual property acquired according to the law.

Basically, this law refers to inventions, trademarks, commercial drawings and models, commercial and industrial secrets, brand names, distinctive appearances of businesses and commercial establishments and any other intellectual creation for agricultural, industrial or commercial use. It also includes vegetal obtainment. Dispositions of this law of apply to both Ecuadorians and foreigners, residing or not in the country.

a. Trademarks

The trademark registration application should be presented at the National Directorate of Intellectual Property and will contain only one international class of products or services.

The first request to register a trademark presented in a member country of the World Trade Organization, the Andean Community or the Paris Agreement for the Protection of Industrial Property, will grant the applicant the priority right for a period of six months until the same trademark register application is filed in Ecuador. This request could not refer to different or additional products than those contained in the first request.

The right for exclusive use of a trademark will be acquired at the National Board of Intellectual Property. A trademark's register will have a ten-year validity from the date of its concession and it could be renovated. A trademark's renovation has to be requested at the same agency, within six months prior to its expiration.

b. Brand names

Brand names can be registered at the **National Board of Intellectual Property**, for which the same procedure for trademarks registration is needed. This registration represents a presumption for the

~~holder's~~ benefit. However, the right for exclusive use is created by the public and continuous use in trade, at least for six months of the brand name. Brand names will be protected without the obligation of register. The register of a brand name does not have a maximum validity time.

SECTION IX. IMPORT PROCEDURES

In order to clear customs, the following procedure must be carried out:

If the FOB value of the imported goods exceeds US\$ 4000, the owner, consignee or ~~consigner~~, personally or through a customs agent, must to present the declaration in the **Unique Import** Document (DUI).

The Unique Import Document (DUI) must be acquired and after presented to any bank or financial society correspondent to the Central Bank. After establishing the importer's identity, the bank or financial society will accept the document within the two following working days.

The DUI form approved by the bank does not have a validity limit time, is indefinite, except in goods with restrictions. In this case, the validity time is determined by the authorizations or import licenses.

The declaration must be presented in the customs, starting anytime between seven days before to fifteen days after the arrival of the goods. This ~~customs declaration~~ must be accompanied by the following documents:

1. Note of Requisition (mandatory)
2. Authorizations or licenses (if needed): If the type of good demands it, it is necessary to obtain authorizations in the ministry or public entity depending on the case (See Section VI. Other Regulations and Requirements).
3. Insurance (if needed).
4. Import Verification Request (SVI) (if needed): Just for goods which FOB value exceeds US\$4000. The request has to be filled and then presented to the verification company (SGS, Bureau Veritas, Cotecna o ITS) along with the requisition note.
5. Inspection Certificate (CI) (If needed): This certificate is issued by the verification company after having previously issued the SVI, and only in goods exceeding FOB value of US\$4000. According to the Law, if a good enters Ecuador without the CI, it cannot be nationalized.
6. Certificate of Origin (if needed)
7. Shipment **Manifest (mandatory)**
8. Bill of Lading (mandatory)
9. Commercial Invoice (FC) (mandatory)
10. Customs Declaration of Value (DAV) (mandatory): Is an oath that the consigned value is the real one.

*Import documents do not have to be translated into the local language.

The import declaration has to be presented in the respective customs district, which will verify the data and confirm compliance with all requirements. If there are no observations, the declaration will be accepted, and the district will assign a validation number so the procedure may continue. Once the declaration is accepted, it is final and cannot be amended.

The next step is documental revision or visual examination of the goods, to establish its nature, quantity, value and its tariff classification.

In the visual examination, the verification company checks the merchandise, verifies that the security seal has not been violated and compares the declaration with the actual load. If everything is correct, the documental revision takes place. If it is not equal, the verification company will make sure that the difference is within the tolerance margin (maximum 10% of the taxes) and the importer will pay the same upon the totality. Taxes are paid upon the real quantity, but if the difference exceeds 10%, it is considered illegal.

The physic examination generally delays more time than predicted, for which it is recommended to calculate a 30% more of the budget established for customs clearance. It is calculated that 70% of the ~~containers~~ arriving at the port of Guayaquil stay there more than 15 working days.

The documental revision is also carried out by the verification company. This consists in verifying that what was declared is equal to what the accompaniment documents of the DUI stated. If there are no observations, the customs district will authorize the payment of tariffs which will be done through one of the authorized banks for this matter. Subsequently, customs will proceed to confirm this payment and will authorize the delivery of the merchandise.

If there was an obstacle for tax payment, the ~~Ecuadorian Customs Corporation~~ (CAE) demands a guarantee of 20% of the total amount to be paid with a time limit of 60 days.

If in the declaration and documents delivery, only the commercial invoice is missing, for example, the merchandise can be taken out with a guarantee, but the term is only 30 days to present an invoice to the CAE. However, if the Certificate of Origin is missing, it is better to leave the merchandise until the certificate arrives.

Claims upon any customs administrative act, can be presented to the manager within 20 days after it was carried out or notified.

AGRICULTURAL AND LIVESTOCK PRODUCTS IMPORT

The inspection in the country of origin previous to the import shipment is a requirement established in the law. These inspections will be carried out by the verification companies hired for this purpose.

Imports of agricultural and livestock products (except industrialized products) will be carried out only

through ports where SESA animal quarantine officers and plant quarantine officers exist, according to the Law of Animal Health and Law of Plant Health.

Airports: Quito and Guayaquil

Seaports: Guayaquil, Manta, Esmeraldas and Puerto Bolívar.

Land Ports: Tulcán, Macará and Huaquillas.

When the merchandise arrives, a SESA inspector will check and examine the documents, will inspect the product itself to confirm the phytosanitary state, and ~~will issue a merchandise entry license~~.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

MINISTRY OF FOREIGN TRADE, INDUSTRIALIZATION AND FISHING

Address: Av. Amazonas y Eloy Alfaro

Ministerial Office

Phone: 593-2-505-072/ 593-2-529-076

Fax: 593-2-507-549

Contact: *Minister*- Ing. Richard Moss

International Trade Directorate

Phone: 593-2-541-854

Contact: *Director*- Econ. Fabián Andrade Egas

Website: www.micip.gov.ec

MINISTRY OF PUBLIC HEALTH

Address: Juan Larrea 445, A Building, 3rd Floor.

Sanitary Control Directorate

Fax/ Phone: 593-2-541-851

Contact: Dr. Patricio Palomeque

Contact: Dra. Magda Saltos

Fax/Phone: 593-2-236906

Medicines and Food Sanitary Control

Phone: 593-2-544267

General Health Directorate

Phone: 593-2-521746/521277

Fax: 593-2- 504322

Web-site: www.msp.gov.ec

E-mail: msp@accessinter.net

Quito, Ecuador

MINISTRY OF AGRICULTURE AND LIVESTOCK

Address: Av. Amazonas y Eloy Alfaro, MAG Building, Quito
Minister: Ing. Galo Plaza P.

Ecuadorian Animal and Plant Health Service (SESA)

Contact: *Director-* Mr. Ruben Vinueza

Plant Quarantine Directorate

Contact: Ing. Gonzalo Robalino

Animal Health

Contact: Dra. Hipatia Nogales

Agricultural Products Control and Register Division

Contact: Ing. Carlos Navas

Phone: (5932) 256-7232/ 254-3319/254-8823

Fax: (5932) 254-8751/ 222-8448

E-mail: sesa@impsat.net.ec

Domestic and International Trade Directorate

Contact: Dr. Carlos Romero

Fax/ Phone: (5932) 222-8011

Agricultural and Livestock National Directorate

Contact: *Director-* José Antonio Ruíz

Phone: (5932) 255-2646/ 254-8409

Fax: (5932) 250-4833

Phone: (5932) 255-3472

Web-site: www.mag.gov.ec

Quito, Ecuador

ECUADORIAN INSTITUTE OF NORMALIZATION (INEN)

Address: Baquerizo Moreno No. 454 y Almagro

International Normalization Directorate

Contact: Ing. Felipe Urresta

Consumer Control Directorate

Contact: Mr. Henry Troya

Phone: (5932) 252-8556 / 250-1885 / 250-1887

Fax: (5932) 256-7815

e-Mail: inen1@inen.gov.ec

Web-site: www.ecua.net.ec/inen

Quito, Ecuador

NATIONAL HEALTH AND TROPICAL MEDICINE INSTITUTE "LEOPOLDO IZQUIETA PEREZ"

Address: J. Coronel y J. Mascote
Contact: *Director*- Dr. Mario Murgueitio
Contact: *Subdirector*- Dra. Elvira Merchán

Phone: (5934) 228-1045/ 228-1200/ 228-1540/ 228-1944
Fax: (5934) 228-1045
E-Mail: Liprnt@telconet.net
Guayaquil, Ecuador

ECUADORIAN CUSTOMS CORPORATION (CAE)

General Manager Office:

Contact: *General Manager*- Ing. Jaime Santillán Perantes
Address: Av. 25 de Julio Km 4, vía a Puerto Marítimo.
Phone: (5934) 248-0640
Fax: (5934) 248-8894

District Manager Office:

Contact: *District Manager*- Mr. Carlos Huerta
Address: Sea Port
Phone: (5934) 248-1166 / 248-1879

Aero Cargo Deputy Manager Office:

Contact: *District Manager*- Mr. Rafael Compte
Address: Airport "Simón Bolívar".
Phone: (5934) 228-7834 / 228-7827

Deputy Manager Office of Salinas:

Contact: *District Manager*- Mr. Guillermo Pareja Cuscalón
Address: Av. 9 de Octubre 102
Phone: (5934) 278-2643
Guayaquil, Ecuador.

Regional Deputy Manager Office for Customs:

Contact:
Regional Manager- Ab. Eduardo Guerrero
Address: Epsilon Building, 10 de Agosto 1731 y San Gregorio, 4th floor.
Phone: (5932) 255- 7482 / 255-7525

District Manager Office:

Address: Pasaje Amazonas y Río Arajuno.

Phone: (5932) 244-8581 / 245-8715
Quito, Ecuador.

Website: www.corpae.com

E-mail: webmaster@corpae.com / Customer_service@corpae.com

NATIONAL BOARD OF INTELLECTUAL PROPERTY

Address: Av. Amazonas y Eloy Alfaro, Ministry of **External Trade, Industrialization and Fishing Building, 1st floor.**

Contact: National Director- Dr. José Villena Castillo

Department of Trademarks

Contact: *Director-* Dr. Gonzalo Vaca

Department of Patents

Contact: *Director-* Ing. Martha Carvajal

Phone: (5932) 255-1612

Fax: (5932) 254-3894

Quito- Ecuador

APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

U.S. EMBASSY QUITO

USDA/ Foreign Agricultural Service

Address: Av. Colombia #1573 y Queseras del Medio, 3rd floor

Carlos M. Yugcha, Agricultural Specialist

René A. Alarcón, Marketing Specialist

Phone: (5932) 256-4147 / 252-9088

Fax: (5932) 250- 6283/ 250-4888

e-mail: Agquito@fas.usda.gov

Quito, Ecuador.